



SAFETY DATA SHEET

100-0882 - (S)-Duloxetine (Hydrochloride)

Revision Date 15-Sep-2021

Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name (S)-Duloxetine (Hydrochloride)

Other means of identification

Catalog Number 100-0882

UN/ID no. UN2811

Document Number 10000012553

Synonyms LY248686; N-methyl-γS-(1-naphthalenyloxy)-2-thiophenepropanamine, monohydrochloride;

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemical

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc.
Suite 500 - 1618 Station Street
Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 3
Acute toxicity - Dermal	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 1
Serious eye damage/eye irritation	Category 1
Reproductive toxicity	Category 2

Hazards not otherwise classified (HNOC)

Not applicable



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Label elements

Danger

Hazard statements

Toxic if swallowed
Fatal in contact with skin
Fatal if inhaled
Causes serious eye damage
Suspected of damaging fertility or the unborn child



Appearance Crystalline

Physical state Solid

Odor No data available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Do not get in eyes, on skin, or on clothing
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Immediately call a POISON CENTER or doctor
IF ON SKIN: Wash with plenty of water and soap
Immediately call a POISON CENTER or doctor
Take off immediately all contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
Store locked up



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Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Information

Very toxic to aquatic life with long lasting effects

Toxic to aquatic life

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Synonyms

LY248686;. N-methyl-γS-(1-naphthalenyloxy)-2-thiophenepropanamine, monohydrochloride;.

Chemical name	CAS No.	Weight-%
(3S)-N-methyl-3-naphthalen-1-yloxy-3-thiophen-2-yl propan-1-amine hydrochloride	136434-34-9	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice

Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact

Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact

Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Ingestion

Get immediate medical advice/attention. Clean mouth with water and drink afterwards



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plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting.

Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms Burning sensation.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical No information available.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so.



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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Ensure adequate ventilation. Take off contaminated clothing and wash before reuse. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep out of the reach of children. Store locked up. Store in accordance with information listed on the Product Information Sheet (PIS).
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
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Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Tight sealing safety goggles.
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Hand protection	Impervious gloves. Wear suitable gloves.
Skin and body protection	Impervious clothing. Long sleeved clothing. Chemical resistant apron. Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline
Color	No information available
Odor	No data available
Odor threshold	No data available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	Product is not flammable.	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	



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Oxidizing properties No information available

Other Information

Softening point No information available

Molecular weight 333.9

Molecular formula C₁₈H₁₉NOS • HCl

VOC Content (%) No information available

Liquid Density No information available

Bulk density No information available

10. STABILITY AND REACTIVITY

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials Strong acids. Strong oxidizing agents. Strong bases.

Hazardous decomposition products Carbon dioxide (CO₂). Carbon monoxide. Hydrogen chloride gas. Nitrogen oxides (NO_x). Sulphur oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause irreversible damage to eyes.

Skin contact Fatal in contact with skin. (based on components). Specific test data for the substance or mixture is not available. May cause irritation.

Ingestion Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness.



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Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 100.00 mg/kg

ATEmix (dermal) 5.00 mg/kg

ATEmix (inhalation-dust/mist) 0.005 mg/l

Unknown acute toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation May cause skin irritation.

Product Information

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.

Product Information

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity No information available.

Product Information

Carcinogenicity No information available.

Reproductive toxicity Classification based on data available for ingredients.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure No information available.

Product Information

Aspiration hazard No information available.

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12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Product Information

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

DOT

UN/ID no. UN2811
Proper shipping name Toxic solids, organic, n.o.s. ((S)-Duloxetine(hydrochloride))
Hazard class 6.1 Toxic substances
Packing Group I

TDG Not regulated

MEX Not regulated

ICAO (air) Not regulated



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IATA

UN Number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. ((S)-Duloxetine(hydrochloride))
Transport hazard class(es)	6.1 Toxic substances
Packing Group	I

IMDG

UN Number	UN2811
UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. ((S)-Duloxetine(hydrochloride))
Transport hazard class(es)	6.1 Toxic substances
Packing Group	I

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
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Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations This product does not contain any substances regulated by state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 15-Sep-2021

Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.



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End of Safety Data Sheet